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TO: USPTO
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TOTAL NO. OF PAGES INCLUDING COVER: 6

DATE: June 29, 2006

NOTES/COMMENTS:

PLEASE HAND DELIVER

In re Application of: **Seoju Lee**
For Patent For: **"Pegylated Interleukin-10"**
Group Art Unit: **1616**
Attorney Docket No.: **JB01337K** US/ Serial No.: **09/967,223**
Filed: **09/28/2001**
U.S. Patent No.: **7,052,686 B2**

Dear Examiner:

Transmitted here with are:

- **Fax Cover Sheet - 1 Page**
- **Certificate of Transmission under 37 C.F.R. 1.8 PTO/SB/97 – 1 Page**
- **Petition to Correct Errors on Issued Patent Under C.F.R. 1.322 – 1 Page**
- **Certificate of Correction PTO/SB/44 – 1 Page (in duplicate)**
- **Copy of Claim Page of U.S. Patent 7,052,686 B2 – 1 Page**

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Docket Number: JB01337K US
Application No: 09/967,223
Filing Date: 09/28/2001
First Inventor: LEE, Seoju

Certificate of Transmission under 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office

on June 29, 2006
Date

Signature

GRANT E. REED
Typed or printed name of person signing Certificate

41,264
Registration Number, if applicable

908-298-5067
Telephone Number

Note: Each paper must have its own certificate of transmission, or this certificate must identify each submitted paper.

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- Copy of Claim Page of U.S. Patent 7,052,686 B2 – 1 Page

PATENT CASE JB01337K

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of		
Seoju Lee J.		Examiner: Edward J. Webman
Appl. No.:	09/967,223	Group Art Unit: 1616
Filed:	September 28, 2001	
Patent No.:	7,052,686 B2	Issue date: May 30, 2006
For:	Pegylated Interleukin-10	

Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO CORRECT ERROR IN ISSUED PATENT

Petition is hereby made under 37 C.F.R. § 1.322 to correct an error in the claims of the above-identified issued patent. The error is noted on Form PTO/SB/44 enclosed herewith.

Applicants respectfully submit that the error is due to a mistake by the Office. Accordingly, it is believed that no fee is due. Issuance of a Certificate of Correction is respectfully requested. If there are any questions, please contact the undersigned.

June 29, 2006

Respectfully submitted,

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Grant E. Reed
Reg. No. 41,264

Docket Number: JB01337K US
Application No: 09/967,223
Filing Date: 09/28/2001
Express Mail Label:

PTO/SB/44 (04-04)
Approved for use through 04/30/2007. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,052,686 B2
DATED : 05/30/2006
INVENTOR(S) : LEE, Seoju

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

10. A process for preparing a pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 1, comprising mixing the mono-PEG-IL-10 with a pharmaceutically acceptable carrier.

MAILING ADDRESS OF SENDER:
GRANT E. REED, Reg. No. 41,264
Schering-Plough Corporation, Patent Dept, K-6-1, 1990
2000 Galloping Hill Road, Kenilworth NJ 07033-0530

PATENT NO. 7,052,686 B2

No. of additional copies
⇨ 1

DUPLICATE

Docket Number: JB01337K US
Application No: 09/967,223
Filing Date: 09/28/2001
Express Mail Label:

PTO/SB/44 (04-04)
Approved for use through 04/30/2007. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,052,686 B2
DATED : 05/30/2006
INVENTOR(S) : LEE, Seoju

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PATENT NO. 7,052,686 B2

No. of additional copies
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10. A process for preparing a pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 1, comprising mixing the mono-PEG-IL-10 with a pharmaceutically acceptable carrier.

11. The mono-PEG-IL-10 according to claim 1, wherein the IL-10 is human IL-10.

12. A pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 11 and a pharmaceutical carrier.

13. The mono-PEG-IL-10 according to claim 11, wherein the PEG molecule has a molecular weight of 12,000 or 20,000 daltons.

14. A pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 13 and a pharmaceutical carrier.

15. A pharmaceutical composition comprising the mono-PEG-IL-10 according to claim 1 in combination with a pharmaceutically acceptable carrier.

16. A method of treating inflammation in an individual in need of such treatment, comprising administering to the individual a therapeutically effective amount of the pharmaceutical composition according to claim 15.

17. A process for preparing the mono-PEG-IL-10 according to claim 1, comprising the step of:

reacting IL-10 with an activated PEG-aldehyde linker in the presence of a reducing agent to form the mono-PEG-IL-10 under conditions in which the linker is covalently attached to one amino acid residue of the IL-10.

18. The process according to claim 17 wherein:

(a) the reducing agent is sodium cyanoborohydride;

(b) the activated PEG-aldehyde linker is PEG-propionaldehyde;

(c) the PEG is a methoxy-PEG;

(d) the linker is multi-armed;

(e) the ratio of IL-10 to the sodium cyanoborohydride is from about 1:0.5 to 1:50;

(f) the total molecular mass of all PEG comprising the PEG-aldehyde linker is from 3,000 daltons to 60,000 daltons; or

(g) the reacting step is performed at a pH of 5.6 to 7.8.

19. The process according to claim 17, wherein the ratio of IL-10 to the sodium cyanoborohydride is 1:5 to 1:15.

20. The process according to claim 17, wherein the total molecular mass of all PEG comprising the PEG-aldehyde linker is from 10,000 daltons to 36,000 daltons.

21. The process according to claim 17, wherein the reacting step is performed at a pH of 6.3 to 7.5.

22. The process according to claim 17, further comprising a step selected from:

incubating the mono-PEG-IL-10 product in a buffer at pH 5.0 to 9.0; or

treating the mono-PEG-IL-10 product with 0.05 to 0.4 M hydroxylamine HCl salt.

* * * * *